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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,819	06/26/2003	Thomas Nilsson	239639US8	2765

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/603,819

Applicant(s)

NILSSON ET AL.

Examiner

James H. Alstrum-Acevedo

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

**Claims 21-38 are pending.** Receipt and consideration of Applicants' arguments, remarks, and amendments filed on April 12, 2006 is acknowledged.

#### *Specification*

The objection to the abstract of the disclosure for consisting of two paragraphs and 201 words **is withdrawn**, per Applicant's submission of a new abstract and cancellation of the original abstract.

The objection to the disclosure because of the following informality: the title of the disclosure on page 1 is missing the letter "o" in the word "administration" **is maintained**, because the missing letter in the title has not been corrected.

The objection to claim 18 **is rendered moot**, because Applicant has cancelled said claim.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 21-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 21, 26-28, 31, 35, 37 and 38 contain the term "common dose bed."

This term was not present in the original claims or specification as filed, and thus constitutes new matter.

The remaining claims are rejected for depending upon a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1, 2, 5-8, 12-15, and 19-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot, because Applicant has cancelled said claims.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 3, 5, 7, 8, 11, 12, and 18-20 under 35 U.S.C. 102(b) as being anticipated by Haikarainen et al. (WO 00/64519) is moot, because Applicant has cancelled these claims. **New claims 21-24, 26, 31, 33, 35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Haikarainen et al. (WO 00/64519) for the reasons of record on pages 5-6 of the previous office action and further described in the response to arguments section below.**

The rejection of claims 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 2002/005344 A1) is moot, because these claims have been cancelled. **New claim 21-26, 30-35, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 2002/005344 A1) for the reasons of record, described on pages 6-8 of the previous office action and further described in the response to arguments section below.**

The rejection of claims 11-20 under 35 U.S.C. 102(e) as being anticipated by Clarke et al. (US 2002/0103260) is moot, because these claims have been cancelled. **New claim 21-24, 26-33, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al. (US 2002/0103260) for the reasons of record, described on pages 8-9 of the previous office action and further described in the response to arguments section below.**

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 2, 4, 6, and 9-10 under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2002/005344 A1) is moot, because Applicant has cancelled said claims.

The rejection of claims 2, 4, and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Nilsson et al. (U.S. Patent No. 6,422,236) is moot, because Applicant has cancelled said claims.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections of the claims of the instant application rejected on the ground of nonstatutory obviousness-type double patenting as described on pages 13-19 of the previous office action are moot, because Applicant has cancelled said claims. The rejections of the new claims with the copending applications discussed in the previous office action follow and are based upon the reasons of record.

The rejection of the claims of the instant application on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 10/603,818 (copending '818) is withdrawn, because a terminal disclaimer between the instant application and copending '818 has been filed in the prosecution of copending '818.

**Claims 21-29 and 31-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-32, 36-47, and 49-53 of copending Application No. 10/703,505 (copending '505) for the reasons of record.** It is noted that the original claims of copending '505 have been cancelled and that the new claims of copending '505 cited in this rejection have the same or substantially similar scope as the previously cited claims.

**Claims 21-24, 28, 31-33, and 35-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44, 46, 49-55, 59-61, 64-70, and 73 of copending Application No. 10/728,986 (copending '986) for the reasons of record.** It is noted that the original claims of copending '986 have been cancelled and that the new claims of copending '986 cited in this rejection have the same or substantially similar scope as the previously cited claims. It is also noted that the dry, moisture-tight barrier seal described in claims 67-69 reads on a blister pack (i.e. a common dose bed).

**Claims 21-24, 27-33, 35, and 37-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/870,907 (copending '907) in view of Akehurst (U.S. Patent No. 6,303,103) (USPN '103) for the reasons of record.**

Claims 21-24, 26-33, and 35-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 10/870,909 (copending '909) for the reasons of record.

Claims 21-24, 26-33, and 35-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 10/870,945 (copending '945) for the reasons of record.

Claims 31-33 and 35-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 15-17, and 21-23 of copending Application No. 10/921,192 (copending '192) in view of Akehurst (USPN '103) for the reasons of record. It is noted that lactose, recited in claim 21 of copending '192 is an excipient, and that claims 22-23 of copending '192 read on a blister pack.

Claims 31-33 and 35-38 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 10, 13, and 14 of copending Application No. 11/085,523 (copending '523) in view of Akehurst (USPN '103) for the reasons of record.



Claims 21-22 and 31-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 9-11 of copending Application No. 11/049,696 (copending '696); claims 31-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-7, 14, 16-19, and 32-33 of copending Application No. 11/111,888 (copending '888); claims 21-22 and 31-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-8, 15, and 17-18 of copending Application No. 11/272,859 (copending '859). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and thus mutually obvious. Copending '696 and the instant application both recite medical products comprising at least two medicaments (the phrase "at least one glucagon-like peptide" in copending '696 reads on at least two medicaments) loaded in a sealed container, adapted for prolonged pulmonary delivery by inhalation from a dry powder inhaler. The duration of the prolonged delivery recited in claim 2 of copending '696 overlaps with the range recited in claim 22 of the instant application. The difference between applications is that copending '696 recites the limitation that more than 50% by mass of active agents leave the inhaler as fine particles. It would have been obvious to a person of ordinary skill in the art at the time of the instant application that the de-aggregated fine particles recited in claim 21 of the instant application would leave an inhaler as fine particles, thus obviating the aforementioned limitation of copending '696. A similar analysis was used in the determination of obviousness-type double patenting with copending applications '888 and '859. It is noted that

the container described in copending '859 reads on a common dose bed recited in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments, filed April 12, 2006, have been fully considered but they are not persuasive. The Examiner will address the Applicants' arguments as they relate to each of the prior art references of record. The Applicant alleges that Haikarainen is very different from the claimed invention, because Haikarainen's dry powder inhaler (DPI) requires the opening of a container within said DPI, whereas Applicants' invention utilizes a sealed pre-metered dose, wherein the combined dose (comprised of two or medicaments) is released an aerosolized directly from the dose container. The Applicant argues that moisture will enter Haikarainen's device and result in a gradient of medicament over time. This latter argument is unpersuasive because it is not supported by evidence. It is the Examiner's position that the DPI disclosed by Haikarainen inherently comprises a common dose bed in which two or more medicaments are deposited separately, wherein the common dose bed is the air channel of Haikarainen's device through which both medicaments must traverse prior to entering a subject's respiratory tract upon inhalation/actuation of the DPI. Furthermore, the duration of an inhalation upon actuation of Haikarainen's device inherently overlaps with Applicant's definition of prolonged delivery during a single inhalation ranging from 0.01 seconds to 6 seconds. The sequential delivery of medicaments during a single inhalation is also inherent as the different active powders contained

within Haikarainen's would have different aerodynamic properties and thus inherently different times of flight through the DPI prior to inhalation into a subject's respiratory tract. Finally, inhalation reads on aerosolization.

Regarding the Davies reference, the Applicant alleges that Davies does not disclose a common dose bed upon which are deposited two or more medicaments. This argument is unpersuasive, because Davies discloses a blister pack incorporated in his invented DPI, which may contain different medicaments located in sequential blisters and/or different medicament combinations contained within separate sequential blisters. A blister pack is a common dose bed, as evidenced by Applicants' admission to this effect in claim 30, line 2 of the instant application: "...forming a dose bed as a blister pack..."

Regarding the disclosure of Clarke, Applicants argue that Clarke's disclosure merely restates what was discussed by the Applicant in the background section of the instant application and is therefore subject to the same problems. This is found unpersuasive, because Clarke teaches a composition comprising 0.048% w/w formoterol fumarate dihydrate powder, 1.000 % w/w fluticasone propionate powder, and 98.952% w/w lactose monohydrate powder. Lactose monohydrate is an art recognized *biologically acceptable inert substance* (i.e. an excipient). Given the overwhelmingly large proportion of lactose relative to the medicaments in admixture with it, said medicaments are inherently separated by the lactose and do not detrimentally interact because of this physical separation. Furthermore, Clarke discloses that the dry powders may be administered from multi-dose dry powder inhalers in which the compositions are contained within a blister pack. As discussed above, blister packs are common dose beds, per

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Applicants' admission. Therefore, Applicants' arguments against the Clarke reference are found unpersuasive.

Finally, regarding the provisional obviousness-type double patenting rejections of record, unless otherwise stated above, these rejections are maintained; because the instant application is not in condition for allowance and it remains unclear whether this application or another copending application will be in condition for allowance first.

#### ***Other Matter***

The Examiner respectfully suggests changing the words, "interact" and "forming" in claim 27, line 5 to "interacting" and "formation," respectively, to improve how the claim reads. A similar change is respectfully suggested for claim 36, line 3.

#### ***Conclusion***

**The specification is objected. Claims 21-38 are rejected. No claims are allowed.**

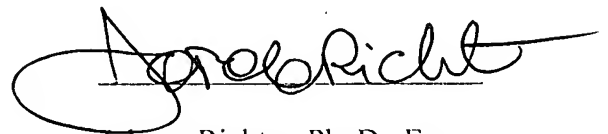
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Johann Richter", written over a horizontal line.

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